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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,259

Applicant(s)

ANNIBALI, NESTOR

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 6-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 4 is/are rejected.
- 7) ☒ Claim(s) 2, 5 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-5 and 24) in the reply filed on March 22, 2004 is acknowledged.

Claims 1-24 are pending in the instant application. Claims 6-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Claims 1-5 and 24 are under examination in the instant application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant Application.

However, Applicant cannot rely upon the foreign priority papers because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. AS a result, the instant application is considered to have a priority date of September 12, 2001 (the filing date) until such time that a translation of the foreign priority document is provided for an accurate determination of priority thereto.

Specification

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the specification contains numerous grammatical errors, and is not in proper idiomatic English. For example, the following sentences appear in the instant application: (a) "As from the development of the recombinant DNA techniques, a wide variety of method for the production of

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insulin in microorganisms has been published in several media" (see for example page 3, lines 6-9); and (b) "Considering the above mentioned difficulties the idea has arose in the experts of cloning the DNA sequence corresponding to the proinsulin or its derivatives wherein the peptide C is represented by fragments having several sizes. These ides have been based in that the presence of the peptide C or its derivatives produced a higher yield of proinsulin correctly folded after the oxidizing step as compared to the yield resulting from the oxidizing of chains A and B by separate" (see for example page 4, lines 5-13). Note that these are only examples of the inconsistencies with proper idiomatic English, and that additional inconsistencies exist throughout the specification that require correction.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

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Additionally, the contents of the specification improperly refer to the claims for descriptive support (see for example page 19, line 7). It is improper to refer to the claims for descriptive support because the claims are subject to amendment, cancellation and/or renumbering throughout the prosecution of the case, thus the description that is relied upon may also change.

Finally, the specification refers to the teachings of a European patent on page 5, line 4; however, the identity of the patent is not disclosed (i.e., there is no patent number given).

Appropriate corrections are required in response to this Office Action.

Claim Objections

Claims 1-5 and 24 are objected to because of the following informalities: the claims contain numerous grammatical and syntax errors. For example, claim 1 states, "wherein said constructions controlling the expression and secretion of human insulin precursor;" this is grammatically incorrect because the verb "controlling" is not in the correct tense (i.e., the verb "control" would be in the proper tense). Furthermore, claim 1 does not begin with an article such as "A" or "The." Additional grammatical and syntax errors occur throughout the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the strain ATCC PTA-2260 is required to practice the invention. As such, the strain must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain. In the instant case, the process to generate the strain that is disclosed in the specification does not appear to be repeatable, nor does it appear the strain is readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

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It is noted that the strain has been deposited; however, the aforementioned statements in compliance with 37 CFR § 1.801-1.809 have not been furnished. Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

This rejection is predicated on the lack of an English translation of the foreign priority document. In the absence of a translation, priority for the instant application can only be acknowledged insofar as the US filing date of the instant application. Additionally, the following interpretations are relied upon in the application of the art, in view of the grammatical and syntax errors present in the instant claims: (a) the term “analogous” is interpreted to mean “analogues;” (b) the claims are interpreted to read on the integration of the first and second DNA constructs into the host cell genome; and (c) the claims are interpreted such that if a DNA construct integrates into multiple locations of an individual host cell, those multiple integrations represent a first and second (and possibly more) DNA constructs within the context of the claimed organism, provided they are capable of directing the expression and secretion of human insulin or an analogue thereof. This is due to the fact that there is nothing in the claims to structurally distinguish the first and second constructs from each other.

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Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Feng *et al.* (WO 200118052 A1; see entire document; henceforth Feng).

Feng teaches a yeast expression system for the production of human insulin analogues, wherein the preferred yeast is the methylotrophic *Pichia pastoris* (see for example page 3, lines 19-26). The yeast strain is constructed in the following manner by first constructing a plasmid having the following elements, in 5'-3' orientation: the AOX1 promoter, the yeast α -mating factor signal (export) peptide, a human insulin gene (or analogue thereof) and a 3' AOX1 termination sequence (see for example Figure 1 and page 2, lines 20-30). This forms a "promoter-signal sequence-insulin" construct. The plasmid/construct is then linearized by restriction endonuclease digestion, and the construct is transformed into a *Pichia* host cell, where multiple copies integrate into the genome (see for example page 2, lines 29-35). Because the host cell contains multiple individual copies of the "promoter-signal sequence-insulin" construct integrated into distinct locations within its genome, the host cell comprises at least a first and a second construct having the capacity to express and secrete human insulin. As such, Feng teaches each and every element of the claimed invention, and thus anticipates the claims.

Allowable Subject Matter


Claims 2, 5 and 24 are objected to as being dependent upon a rejected base claim (claim 1), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David A. Lambertson, Ph.D.
AU 1636